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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,207	12/01/2000	Yoshiyuki Nagai	50026/005002	4421

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EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,207

Applicant(s)

NAGAI ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-13,15-18,20,22,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-13,15-18,20,22,27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09071591.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The rejections based upon 35 USC 102 and 103 are withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 112

Claims 11-12, 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are indefinite because they depend from a cancelled claim. In the interest of compact prosecution, these claims have been treated as if they depended from claim 1. However, this treatment does not relieve applicant of the burden of response to this rejection. Note that, if claims 16-17 depend from claim 1, they become duplicates of claims 4-5.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 27 has been amended to specify that the Sendai vector genome has a deleted or inactivated NP, P, or L gene, and all other genes retained. The passages pointed to as supporting this amendment generally state that any desired gene can be deleted or inactivated, but do not reasonably convey any desire to choose the NP, P, or L gene for deletion or inactivation. The passage on page 15 indicates that modification of these genes may be desirable to enhance or reduce

transcription or replication capabilities, but does not reasonably communicate any desire to eliminate transcription or replication capabilities. Furthermore the specification does not disclose any advantage gained by eliminating transcription or replication or how to use such a disabled virus. In fact, the specification teaches away from eliminating the replication capabilities, see e.g. page 2 lines 10-16, especially lines 15-16. Therefore the amendment to claim 27 is concluded to introduce new matter.

Double Patenting

Claims 7-9, 11, 12, 20, 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,514,728. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the previously patented methods and products, or because the patent claims recite a process using products that are encompassed by the instant claims.

Applicant argues that the instant claims do not overlap in scope with the patent claims, because the instant claims are directed to a method of producing a recombinant Sendai virus vector and kit for performing same, and the patent claims are directed to a method for producing a cytokine and method components thereof. In response to this argument, the rejection is withdrawn for the claims directed to a method of producing a vector. However, claims 11 and 12 are, respectively, drawn to a method of producing a foreign protein and an allantoic fluid comprising a foreign protein and Sendai virus particles; these are still seen as encompassing the previously patented method of

producing a cytokine, and the previously patented allantoic fluid containing a cytokine made from an egg infected with a recombinant Sendai virus encoding a cytokine.

Claims 1, 4-11, 13, 15-18, 20, 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,723,532 for the same reasons as the provisional rejection over claims 7-10, 26-47 of copending Application No. 09/070,938. The rejection of record is no longer provisional, because the copending application has issued. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the patent claims to recombinant dissemination-defective Sendai virus vector and associated products and methods of use overlap in scope with the broadly claimed recombinant Sendai virus vector and associated products and methods of use claimed in this application.

Claim 7 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 of U.S. Patent No. 6,645,760, for the same reason as the provisional rejection over claims 6, 8 of copending Application No. 09/471,840. The rejection of record is no longer provisional, because the copending application has issued. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the instant claims encompass the subject matter of the claims previously allowed in the copending application.

Claims 1, 4-6, 13, 16, 17, 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent 6,746,860, for the same reasons as the provisional rejection over claims 1-4, 8 of

compending Application No. 09/702,498. The rejection of record is no longer provisional, because the compending application has issued. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims read upon recombinant Sendai vector with an insert prior to the NP gene.

Regarding the provisional double patenting rejections repeated below, applicant argues that MPEP 706.02(k) states that the provisional rejection should be made in the later filed application, and should be withdrawn from this earlier filed application. However, MPEP 706.02(k) is irrelevant because it deals with using the pending application provisionally as prior art under 35 USC 102(e), not with double patenting. Double patenting is discussed in MPEP 804. Provisional double patenting is not based upon the considerations of 35 USC 102(e) or 103, but is based upon a judicially created doctrine grounded in public policy (a policy reflected in the statutory language of 35 USC 101) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. For this reason this argument is not convincing and the rejections are maintained. However, once provisional double patenting rejections constitute the only remaining issue, it is proper to withdraw the rejections in one of the two applications (i.e. in this application if it is the first to mature).

Claims 1, 4-6, 11-13, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 11, 12, 14, 20, 21 of compending Application No. 09/132,521. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with a chemokine gene and methods of use overlap in scope with the broadly claimed recombinant Sendai virus vector and methods of use claimed in this application.

Claims 1, 4-6, 13, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 16-19, 46-49, 54-57 of copending Application No. 09/823,699. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with HIV genes overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

Claims 1, 4-6, 13, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 09/843,922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to negative-sense RNA viral vector overlap in scope with the recombinant Sendai virus vector. Although copending claim 16 does not recite Sendai virus, it is an obvious embodiment because other claims specifically recite Sendai virus, e.g. claim 15.

Claims 1, 4-6, 12, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 8 of copending Application No.10/111,356. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with a CTFR gene

overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

Claims 1, 4-6, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-13 of copending Application No. 10/181,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with a foreign gene overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

Claims 1, 4-6, 13, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of copending Application No. 10/312,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with a gene for a renal cell overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

The provisional rejection of claims 1, 4-5, 16, 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/316,538 is withdrawn in view of the amendment to the copending claims.

Claims 1, 4-6, 13, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-7 of copending Application No. 10/316,535. Although the conflicting claims are not identical, they are not patentably distinct from each other because in view of Gotoh et al (Virology 171:434-443, 1989). Although the conflicting claims are not identical, they are not

patentably distinct from each other because Gotoh teaches that a ribonucleoprotein complex was known to be involved in recovery of infectious Sendai virus genomes in the prior art. Therefore claims to a Sendai vector are seen as obvious over claims to a complex containing the Sendai vector.

Claims 1, 4-6, 13, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 7 of copending Application No.10/444,661. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with an angiogenic gene overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

Claims 1, 4-6, 13, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 7 of copending Application No. 09/720,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to a negative-sense RNA viral vector overlap in scope with the Sendai virus vector claimed in this application.

Claims 1, 4-6, 13, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-14 of copending Application No.10/398,598. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to a paramyxovirus vector, specifically Sendai, overlap in scope with the Sendai virus vector claimed in this application.

The above rejections are all provisional obviousness-type double patenting rejections, because the conflicting claims have not in fact been patented.

If applicant is aware of any additional copending applications with claims not patentably distinct from the instant claims, applicant has a duty to disclose them, as the existence of such applications is information material to patentability of this application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/3/04


MARY E. MOSHER
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